UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,209	01/27/2006	William Charman	66307358	5439

25269 7590 11/25/2009
DYKEMA GOSSETT PLLC
FRANKLIN SQUARE, THIRD FLOOR WEST
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,209	CHARMAN ET AL.	
	Examiner	**Art Unit**	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed June 22, 2009. **Claims 1-14 and 16-22 are pending.** **<u>Claims 1-14 and 16-22 are under consideration in the instant office action</u>**. Claim 15 is cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is made FINAL.

Withdrawn Rejections

Applicant's amendments and arguments filed on 06/22/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

New Claim Objection

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Instant claim 1 was amended to recite the pharmaceutically acceptable oil comprises a mono-, di-, or triglyceride, or mixtures thereof. Similarly, instant claim 7 which depends on claim 1 recites the pharmaceutically acceptable oil is a mono-, di-, or triglyceride, or mixtures thereof, which is not further limiting.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-4, 7, 9-10, 12-14, 16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. (US Patent No. 4999198, IDS reference) in view of Zecchino et al. (WO 01/62214, IDS reference) as evidenced by Final report on the safety assessment of peanut (Arachis Hypogaea) oil etc., International Journal of Toxicology, 20(2):65-77, 2001.

Applicant Claims

Applicant claims in instant claim1 biliquid foam comprising a hydrophilic phase, pharmaceutically acceptable oil, a poorly water-soluble drug and a surfactant at the instantly claimed percentages, wherein the pharmaceutically acceptable oil comprises a mon-, di-, or triglyceride or mixture thereof. Instant claim 2 recites the system of claim 1 wherein the hydrophilic phase is aqueous. Instant claim 3 recites the system of claim 2 wherein the aqueous phase is water. Instant claim 4 recites the system of claim 2 wherein the aqueous phase contains a salt or a co-solvent. Instant claim 7 recites the system of claim 1 wherein the pharmaceutically acceptable oil is a mono-, di-, or triglyceride or a mixture thereof. Instant claim 9 recites the system of claim 1 wherein the surfactant is selected from the instantly claimed list. Instant claim 10 recites the system of claim 1 which includes a co-emulsifier. Instant claim 12 recites the system of claim 1 wherein the discontinuous phase comprises 85-96% of the biliquid foam. Instant claim 13 recites the system of claim 12 wherein the discontinuous phase comprises 90-95% of the biliquid foam. Instant claim 14 recites the system of claim 1 wherein the hydrophilic phase comprises 2-10% of the biliquid foam. Instant claim 16 recites the system of claim 1 wherein the drug is selected from the instantly claimed list. Instant claim 22 recites the system of claim 1 for use in oral administration to humans or animals.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Barnett et al. teach polyaphron systems were prepared using oils in order to determine the most stable formulation (column, lines 23-24). A solution containing **2000 ppm of sodium lauryl sulfate in water** was used to produce **a form in a foam** generator

such as a venturi, cyclone or other high shear device for introducing a gas into a liquid (column 2, lines 24-28). The gas phase of the foam was gradually replaced with **100 mL of drug-charged oil** containing 1 drop of **<u>Tergitol 15-S surfactant</u>** by slowing adding **<u>the oil to 5 mL of foam</u>** with stirring (column 2, lines 28-32). When 1 ml of foam was used, it was possible to make polyaphrons with all of the oils. However, the systems were not appreciably stable for any significant period of time, with the exception of the **<u>peanut and mineral oils</u>** (column 2, lines 32-33). When **<u>5 mL of foam</u>** was used, all systems were initially stable, with the mineral and peanut oil systems proving superior in this regard (column 2, lines 36-38). Systems prepared at this level of foam were thicker and lighter in color, indicating a finer dispersion (column 2, lines 38-40). As a result of these trials, mineral and peanut oil polyaphron systems were selected for release trails (column 2, lines 40-42). Release studies of the peanut and mineral oil systems were performed using **<u>150 mg of scopolamine free base</u>** in 100 mL of oil containing 1 drop of Tergitol 15-S surfactant and 5 mL of foam to form a polyaphron (column 2, lines 43-46). In the preferred embodiment the oil (or disperse phase) is usually present in the amounts **<u>exceeding 80%</u>** so that the system behaves like a gel (column 1, lines 61-63). With regard to the limitation reciting as the oil comprises a mono-, di-, or triglyceride or mixtures thereof Barnett et al. teach the incorporation of peanut oil which comprises a mono-, di-, or triglyceride as evidenced by International Journal of Toxicology, 20(2):65-77, 2001 (see abstract and page 66).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Barnett et al. teach the incorporation of water and surfactant in the preparation of the foam, Barnett et al. do not explicitly teach the amount of water and surfactant. The examiner notes that it is impossible to calculate percent weight amount of the hydrophilic phase and also the surfactant since it is not clear the amount of water and surfactant in the final biliquid foam. These deficiencies are cured by Zecchino et al.

Zecchino et al. teach a biliquid foam suitable for use in pharmaceutical and other industries (abstract). Moreover, Zecchino et al. teach that the typical components of **a biliquid foam are water, oil and one or more surfactants** (page 4, lines 19-20). Zecchino et al. teach **the aqueous phase may constitute from about 5 to about 50% by weight** of the foam composition (page 4, lines 20-23). Zecchino et al. teach that the amount of surfactant is preferably **no more than about 1 % by weight of** the oil phase of the foam (page 5, lines 18-20). Zecchino et al. teach the compositions may be used for the delivery of other agents such as **antiviral, antibiotics anti-inflammatory** etc., (page 6, lines 10-16).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Barnett et al. via the incorporation of hydrophilic phase and surfactant in amounts as recited in instant claim 1 in a biliquid foam because Zecchino et al. teach the incorporation of both aqueous medium and a surfactant for preparing biliquid foam for use in pharmaceutical and other industries in amounts that overlap or lie within the instantly claimed amounts. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior

art” a *prima facie* case of obviousness exists *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). With regard to the recitation in the preamble “an oral drug delivery system”, it is the examiner’s position that the recitation is an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the biliquid foams taught by Barnett et al. and Zecchino et al. given the fact that the biliquid foams comprise water, oil, and surfactant, as in the instantly claimed invention, they are capable of being used as an oral drug delivery system. Additionally, the ingredients incorporated in the biliquid foams taught by Barnett et al. and Zecchino et al. do not contain any toxic agents, therefore, it is the examiner's position that the bilquid foams taught by the prior arts are capable of performing the instantly recited intended function. With respect to instant claim 22, the limitation is a product-by-process recitation “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from

a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since the product has been rendered obvious by the above teachings the limitation recited in instant claim 22 has also been rendered obvious by the prior art teachings.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. (US Patent No. 4999198) in view of Zecchino et al. (WO 01/62214, IDS reference) and Wheeler et al. (WO 97/332559 IDS reference).

Applicant Claims

The claimed subject matter of instant claims 1 and 7 are set forth above. Instant claim 5 recites the system of claim 1 wherein the hydrophilic phase is non-aqueous. Instant claim 6 recites the system of claim 5 wherein the non-aqueous solvent is selected from the instantly claimed list. Instant claim 8 recites the system of claim 7 wherein the mono-, di-, or triglycerides have carbon chain of 6-22 carbons.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Barnett et al. and Zecchino et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Barnett et al. and Zecchino et al. do not teach the incorporation of non-aqueous co-solvents such as those listed in instant claim 6. Barnett et al. and Zecchino et al. do not teach incorporation of the pharmaceutically acceptable oils listed in instant claim 8. These deficiencies are cured by Wheeler et al. (WO 97/332559).

Wheeler et al. teach a biliquid foam suitable for use in pharmaceutical and other industries (abstract). Moreover, Wheeler discloses the incorporation of an alcohol such as ethanol or propanol, a glycol (for example propylene glycol), glycerin, or other acceptable water soluble materials in the hydrophilic phase (page 4). The examiner notes that these are both examples of hydrophilic non-aqueous solvents and of co-solvents. Caprylic/capric triglyceride is listed by Wheeler et al. as an acceptable oil. The examiner notes that caprylic/capric triglycerides have carbon chains of 8 and 10 carbons.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to substitute a triglyceride for the peanut oil or mineral oil taught by Barnett et al. and Zecchino et al. because Wheeler et al. teaches the use of caprylic/capric triglycerides in biliquid foams. An ordinary skilled artisan would have been motivated to substitute caprlic/capric triglycerides for peanut oil or mineral oil because both are pharmaceutically acceptable oils. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of Barnett et al. and Zecchino et al., and Wheeler et al., because Barnett et al., Zecchino et al., and Wheeler et

al. teach the preparation of biliquid foams for use with pharmaceuticals which contain pharmaceutically acceptable oils.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the present invention was made to include an aliphatic alcohol, glycol, etc. because Wheeler et al. teach the incorporation of such hydrophilic solvents in biliquid foam. The skilled artisan would have been motivated to incorporate such solvents in order to enhance the solubility of poorly soluble, e.g., drugs. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of Barnett et al., Zecchino et al., and Wheeler et al., because Barnett et al., Zecchino et al., and Wheeler et al. teach the preparation of biliquid foams for use with pharmaceuticals which contain a hydrophilic phase.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. (US Patent No. 4999198) in view of Zecchino et al. (WO 01/62214, IDS reference) and Leigh et al. (US Patent No. 6599527).

Applicant Claims

The claimed subject matter of instant claims 1 and 10 are set forth above. Instant claim 11 recites the system of claim 10 wherein the co-emulsifier is a phosphoglyceride or a phospholipid.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Barnett et al. and Zecchino et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Barnett et al. and Zecchino et al. do not teach the incorporation of the co-emulsifiers listed in instant claim 11. This deficiency is cured by Leigh et al.

Leigh et al. teach pharmaceutical compositions **for the improved absorption of lipophilic drugs which comprise phospholipids such as phosphatidylcholine and mono-acyl phosphatidyl choline** (abstract).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Barnett et al. and Zecchino et al. to substitute a phospholipid for Tergitol 15-S surfactant or sodium lauryl sulfate as the co-emulsifier because substitution of one emulsifier for another is within the purview of the skilled artisan . An ordinary skilled artisan would have been motivated to incorporate the phospholipid because phospholipids enhance the absorption of and bioavailability of lipophilic drugs (Leigh et al., column 5, lines 39-50). Moreover the absorption, transport and pharmacokinetics of phospholipids are well-known (Leigh et al., column 5, lines 51-21). Such phospholipids as, e.g., phosphatidylcholine and mono-

acyl phosphatidyl choline are endogenous compounds and, therefore, would be expected to have beneficial rather than adverse side effects (Leigh et al., column 6, lines 1-6). An ordinary skilled artisan would have had a reasonable expectation of success upon combining Barnett et al. and Zecchino et al., and Leigh et al., because Barnett et al., Zecchino et al. and Leigh et al. teach pharmaceutical compositions containing poorly water-soluble drugs.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. (US Patent No. 4999198) in view of Zecchino et al. (WO 01/62214, IDS reference) and Metziger et al. (US Patent 5952383).

Applicant Claims

The claimed subject matter of instant claim 1 are set forth above. Instant claim 17 recites the system of claim 1 which is in a unit dosage form. Instant claim 18 recites system of claim 17 wherein capsules are filled with the biliquid foam. Instant claim 19 recites the system of claim 18 wherein the capsules are hard or soft gelatin. Instant claim 20 recites the system of claim 1 which is in the form of a dilutable concentrate. Instant claim 21 recites the system of claim 20 which is dilutable in a co-solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Barnett et al. and Zecchino et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Barnett et al. and Zecchino et al. do not teach gelatin capsules containing the biliquid foam. This deficiency is cured by Metziger et al.

Metziger et al. teach pharmaceutical compositions for oral administration containing a medicinal product that is insoluble or sparingly soluble in water (abstract). The composition contains the pharmaceutical agent, an oil such as a triglyceride of 8-12 carbons and a surfactant such as a nonionic surfactant in addition to other ingredients (see claims 1, 2 and 5). The composition can then be formed into soft or hard gelatin capsules (see claims 9 and 11).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Barnett et al. and Zecchino et al. via incorporating the composition containing the poorly water-soluble drug in a capsule because Metziger et al. teach the incorporation of such poorly water-soluble drugs in gelatin capsules (see claims 1, 9 and 11). An ordinary skilled artisan would have been motivated to incorporate the composition in a capsule because capsules are commonly known and commonly used pharmaceutically acceptable forms. An ordinary skilled artisan would have had a reasonable expectation of success upon combining Barnett et al. and Zecchino et al., and Metziger et al., because Barnett et al. and Zecchino et al., and Metziger et al. teach pharmaceutical compositions containing poorly water-

soluble drugs. Moreover, use of one pharmaceutically acceptable form in place of another similar pharmaceutically acceptable form is within the purview of the skilled artisan.

It would have been *prima facie* obvious to the ordinary skilled artisan to form a concentrate of the composition disclosed in claim 1 because concentrates are convenient to store and to work with. It would have also been *prima facie* obvious to the skilled artisan to dilute the concentrate in a suitable co-solvent because concentrates are diluted prior to use. The skilled artisan would have been motivated to form a concentrated which can be diluted in a co-solvent because such concentrates which are then diluted are conventionally known in the pharmaceutical industry and are used for a wide variety of drug compositions. The skilled artisan would have had a reasonable expectation of success in preparing both the concentrated and dilute forms because concentrates and dilutes are generally easy to make and use.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-14 and 16-22 are rejected. Claim 15 is cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 11/16/09

/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619